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10/695,661	10/28/2003	Gerald Czygan	117163.00094	4060

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,661	CZYGAN, GERALD	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/09/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Preliminary Amendment to the Specification, which was received by the Office on May 13, 2004.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 9, 2004 has been acknowledged and is being considered by the Examiner.

Drawings

3. The drawings are objected to because the unlabeled rectangular boxes shown in Figure 1 should both be provided with descriptive text. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because it contains confusing language and/or terminology. Specifically, the abstract is not clear as to what is new in the art to which the invention pertains. The Examiner suggests revision of the Abstract to include the device's organization and operation in a clear, concise manner. The Examiner also suggests omission of any phrases which can be implied as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b)

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification much include proper antecedent basis for "wherein the stimulation outcome monitoring means, at least after delivery of a stimulation pulse, is connected to the electrode connection and is adapted to detect the short-circuit current or a parameter linked to one of said parameters". Specifically, it is unclear what "said parameters" means and how the short-circuit current is used to adjust the strength of the stimulation pulses. In addition, the disclosure fails to provide support and/or discussion of how a measured time interval (between the administration of a stimulation pulse and the occurrence of a stimulation outcome) is used to adjust and/or set the strength of the stimulation pulse. It is also unclear as to what thresholds are used specifically by the threshold detector. Appropriate correction is required.

6. The disclosure is objected to because of the following informalities: there appears to be numerous typographical and inadvertent errors throughout. All letters of each heading throughout the disclosure should be capitalized. The specification is replete with typographical errors too numerous to mention specifically, however, an example of a typographical error

existing in the specification appears at page 3, paragraphs 6-7. The Examiner suggests changing the references to the U.S. Patents to be sometime similar to "for example from U.S. Patents Nos. 5,350,410, 5,411,533," etc..

7. The Examiner suggests a complete revisiting and revision of the specification to eliminate typographical errors and to provide antecedent basis for all claimed subject matter as discussed above. Appropriate corrections are required.

Claim Objections

8. Claim 1 is objected to because of the following informalities: there appears to be numerous typographical errors throughout the claim. The Examiner suggests rewriting the first 23 lines of the claim as follows. Appropriate correction is required.

> A device for electrostimulation of body tissue through a stimulation electrode, comprising:
>
> an energy storage means for providing electrical stimulation energy to the stimulation electrode from an energy source;
>
> an electrode connection for connecting the stimulation electrode to the device for delivering electrical stimulation pulses to the body tissue;
>
> a first switch with which the energy storage means is switchably connected to the electrode connection for the delivery of a stimulation pulse;
>
> a means for monitoring stimulation outcome;
>
> a short-circuit switch with which the electrode connection, after delivery of the stimulation pulse is switchably and at least indirectly connected to a ground potential such that, in the case of a connected and implanted electrode line, a capacitance can be discharged by way of the body tissue, wherein the capacitance includes at least on Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue; and
>
> a control unit connected to at least the first switch and the short-circuit switch for switching the respective switches and which is adapted to separate the electrode

connection from the energy storage means after delivery of the stimulation pulse and at least indirectly connect the electrode connection to the ground potential;

wherein the stimulation outcome monitoring means ....

As to the lines 23-27 of Claim 1, the Examiner makes reference to the 35 U.S.C. 112, second paragraph rejection set forth below in this Office Action.

9. Claim 1 is also objected to for omitting essential elements, such omission amounting to a gap between the elements as evidenced by dependant claims 17 and 60-64. The omitted elements are: the switch (depicted in Fig. 1) that switch-ably connects the energy storage means (i.e. the reservoir capacitor) to the energy source (i.e. the battery and/or equivalent). The Examiner suggests adding this limitation to claim 1 and changing the reference to the "first switch" at the seventh line of the claim to read "a second switch".

10. Applicant is advised that should claim 4 be found allowable, claim 19 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Applicant is advised that should claim 5 be found allowable, claims 20-21 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

12. Applicant is advised that should claim 6 be found allowable, claims 24-25 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof. When two claims in an

application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The lack of enablement situations are too numerous to mention specifically, however, examples are as follows: it is unclear as to how the invention works and/or functions within a device which applies electrostimulation to body tissue. The Examiner is unsure of what exactly causes the control unit to adjust and/or set the strength of the stimulation pulses. The Examiner believes it is one or a combination of the following:

a.) A detected decrease in voltage with respect to time where the decrease is greater than a specified threshold is used.

b.) A detected increase in short-circuit/discharge/dump current where the increase is greater than a specified threshold is used.

c.) A detected voltage is differentiated and then somehow applied to adjust the strength of the stimulation pulses.

d.) A change in myocardial impedance is used.

e.) A time duration is used.

In reference to situations a. and b. discussed above, the specification fails to provide support and/or discussion of what exact thresholds are used for comparison, how the comparison is accomplished and what signals are sent to the control unit to adjust the stimulation pulses. Furthermore, it is not specified how the stimulation is adjusted. Is the strength increased when there is a decrease in voltage greater than a specified threshold or is the strength decreased? Is the strength of the pulses increased when there is an increase in current greater than a specified threshold or is the strength of the pulses decreased? In reference to situation c.) discussed above it is unclear from the specification what voltage is being differentiated and how it is used to adjust the stimulation pulses. In reference to situation d.) although there is disclosure relating detected myocardial impedance to the voltage and current discussed above, there is no disclosure relating to how such changes in myocardial impedance are being sensed, detected or used to satisfy the requirements of the invention. In reference to situation e.) there is no disclosure relating to any time durations being used to satisfy the requirements of the invention. In addition, in reference to the adjustment of the strength of the stimulation pulses it is unclear as to whether strength adjustments are accomplished via amplitude adjustments and/or pulse width changes.

As mentioned, this is only an example of the issues regarding the lack of enablement in the specification and the Examiner suggests a complete revisiting and revision of the specification in order to provide enablement in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Appropriate corrections are required.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The indefinite language throughout claims 1-64 is too numerous to mention specifically, however examples are as follows.

Regarding the last five lines of Claim 1, the Examiner is unsure of what is actually being claimed (i.e. is "configuration" synonymous with detection of voltage with respect to time). The Examiner is also unsure of the limitation "at the capacitance" in the 25th line of the claim. Is this the coupling capacitance, the Helmholtz capacitance or the combination thereof? The Examiner suggests defining "a configuration in respect of time of a voltage at the capacitance" in more conventional language as well known in the art. The Examiner also suggests defining what a configuration of the short-circuit current is. Is this the strength of the current or any parameter well known in the art representative of current? Regarding Claim 2, the Examiner suggests defining a "characteristic drop in the configuration in respect of time of the detected voltage".

In reference to all claims with include limitations pertaining to a voltage being detected "at the capacitance" it is unclear whether this capacitance is only the coupling capacitance, the Helmholtz capacitance or a combination thereof. In addition, these claims appear to be a contradiction of the independent claim because it seems that a voltage versus time is being detected. The Examiner is unsure whether instantaneous voltage or voltage versus time is included in the limitations of Claim 1. One of ordinary skill in the art knows that voltage is

usually measured between two nodes of a circuit. The Examiner suggests making reference to this in the disclosure and/or the claims so that where the voltage is being measured exactly may be determined (see Fig. 1).

In reference to Claim 9, it is unclear whether the threshold value detector is using a threshold corresponding to the derivative of a detected voltage versus time or an instantaneous voltage value. In addition this claim is confusing because it fails to provide support for the coupling capacitor being connected in such a way to permit the reservoir capacitor to be used to administer stimulation pulses via the electrode connection.

As mentioned above, these are only examples and all claims must be revisited and revised as necessary.

17. Claims 1-64 are replete with antecedent basis problems too numerous to mention specifically, however, examples are as follows: Claim 1 recites the limitation "said parameters" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. It appears that the recitation of "a parameter" in the second to last line of the claim is not the same limitation as "said parameters" in the last line of the claim, thus there is a lack of antecedent basis. Claims 17 and 60-64 recite the limitation "the capacitor" in the third line of each claim. There is insufficient antecedent basis for this limitation and the Examiner is unsure as to which capacitor is being referred to. As mentioned above, these are only examples and all claims must be revisited and revised as necessary.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. In view of the Claim Objections above and further in view of the 35 U.S.C. 112, first and second paragraph rejections above, the following rejections are based on prior art which can be applied to the claims as to the best understanding of the Examiner.

20. Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pons et al. (U.S. 2002/0147477) (herein Pons) in view of Paul et al. (U.S. 5,735,883) (herein Paul). Pons discloses a circuit for delivering a back-up stimulation voltage in a cycle to cycle capture test for an active implantable medical device such as a pacemaker, defibrillator and/or cardiovertor or a multisite electrostimulation device having an enhanced circuit for delivering back-up stimulation pulses. The device of Pons comprises a first stimulation stage having a output capacitor, read as a reservoir capacitor 12, a charging circuit 14 to charge the reservoir capacitor 12 to a first predetermined voltage V1 for the stimulation that is close to the threshold of effectiveness for the stimulation of the patient. The device of Pons further comprises a first switch 18 that is able to connect the reservoir capacitor 12 to a stimulation terminal, read as an electrode connection 16 of the device for connecting stimulation electrodes for delivering electrical stimulation pulses to the body tissue. Pons further discloses a capture test circuit, read as a means for monitoring stimulation outcome that is able to determine, after delivery of stimulation, whether the stimulation was effective or if, on the contrary, there was loss of capture (see Pons Abstract, Figs. 1-2, page 2, paragraphs 16-22 and page 3, paragraphs 22-36).

Pons discloses the claimed invention as discussed above except it is not specified that the energy source include a charge pump. It would have been obvious to one having ordinary skill

in the art at the time the invention was made to modify the device as taught by Pons, with a charge pump since it was known in the art that charge pumps are used to provide a means to multiply or otherwise step up a voltage provided by a typical battery to a reservoir capacitor for powering an implantable medical device such as a pacemaker.

Pons discloses the claimed invention as discussed above except that it is not specified how exactly the means for monitoring stimulation outcome is able to determine, after delivery of stimulation, whether the stimulation was effective or if, on the contrary, there was loss of capture. Paul, however, discloses an implantable pacemaker with an apparatus for detecting capture or adjusting the strength or duration of pacing pulses by assessing the mechanical evoked response that may be distinctly sensed through impedance sensing, pressure sensing, plethysmography or other suitable methods. When capture is to be detected or the strength or duration of the pacing pulses is to be adjusted via the apparatus of Paul, two pacing pulses are delivered to the heart in each cycle of a series of cardiac cycles where the first pulse is varied in strength or duration or both and the second pulse is maintained at a consistently high strength or duration to assure capture. The apparatus of Paul measures the impedance of the heart which is read as a parameter linked to one of said parameters of the configuration due to Applicant's disclosure page 4, paragraph 10. The impedance measuring of Paul is done during a time window following the first pulse, which is predicted to include a recognizable feature of the impedance waveform of the heart following a stimulating pulse. The magnitude of the first pulse is gradually changed until capture is lost. When the stimulation effect of the first pulse on the heart changes, the impedance measured during the window will change distinctly, indicating that a stimulus threshold has been detected. Paul teaches that impedance measurements may be used

for adjustment of the strength of the stimulation pulses as a preferred method over traditional evoked response sensing (see Paul Abstract, column 1, lines 35-67, column 2, lines 1-20, column 3, lines 6-67 and column 4, lines 1-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pons in view of Paul to use measured myocardium impedance to adjust and/or set stimulation pulse strength since impedance measurements may be more reliably measured than traditional evoked response capture determinations.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Condie et al. (U.S. 5,713,933) teaches the use of cardiac impedance measurements to adjust stimulation pulse strength.

Meier (U.S. 6,522,924) teaches the use of a sensor arranged at the myocardium for checking stimulation success at the heart by detecting the myocardial impedance pattern immediately after a stimulation pulse output and still within the diastolic phase of the heart, and controlling the stimulation pulse output based thereon.

Paul et al. (U.S. 5,713,931) (herein Paul '931) teaches that the use of charge pumps to charge reservoir capacitors in an implantable medical device.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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